

CLAIMS

- 1) Powders for inhalation of insulin obtained by spray drying a clear solution of insulin at pH under the isoelectric point of insulin where the 90% of microparticles showing particle size lower than 9 μm as volume diameter.
- 5 2) Powders for inhalation of insulin obtained as Claim 1 having packing characteristics measured as tapped density lower than 0.2 g/cm³.
- 3) Powders for inhalation of insulin obtained by spray drying a clear solution of insulin at pH under the insulin isoelectric point having microparticles showing particle shape defined corrugated or raisin like.
- 10 4) Powders for inhalation of insulin obtained by spray drying a clear solution of insulin at pH under the insulin isoelectric point having respirable fraction measured as fraction lower than 5 μm as aerodynamic diameter was more than 80%
- 5 5) Microparticles according to claim 1 where a clear solution of insulin and excipients having a pH under the isoelectric point of insulin is spray dried.
- 6) Microparticles according to claim 1 where the insulin solutions from which they are obtained have a pH preferably lower than 5.4.
- 7) Microparticles according to claim 1 where the preferred excipients are saccharides, polysaccharides, aminoacids, phospholipids and polyalcohol the
20 more preferred of them is mannitol.
- 8) Microparticles according to claim 1 where the acid used for dissolution of insulin is a mineral acid such as 0.01 N hydrochloric acid.
- 9) Microparticles obtained by spray drying a clear acidic solution of a therapeutic drug where the volatile organic acids used for dissolution of the said drug are
25 partially evaporated during spray drying leaving particles that dissolved in distilled water give rise to a solution having pH higher than the original value.
- 10) Microparticles according to claim 1 where the acid used for dissolution of insulin is a volatile organic acid.
- 11) Microparticles according to claim 1 where the acids are used for dissolution of
30 insulin is a volatile organic acid as diluted acetic acid.
- 12) Microparticles according to claim 1 consisting essentially of insulin and the salts formed from the acids used for the insulin dissolution.

- 13) Microparticles according to any claim from 1 wherein the microparticles contain less of 10 % salt by weight of total solids.
- 14) Microparticles according to claim 1 where the insulin is amorphous.
- 15) Microparticles according to previous claims having a particle size in the
5 respiratory range allowing therapeutic application through administration to the lung.
- 16) A process according to claim 1 wherein the solution to be spray dried contains from 5 up to 100 mg per ml of insulin.